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Risk factors for defaulting from tuberculosis treatment: a prospective cohort study of 301 cases in The Gambia

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SUMMARY

SETTING: An urban tuberculosis (TB) clinic, The Gambia.
OBJECTIVE: To identify patient characteristics associated with increased rates of defaulting from treatment, specifically knowledge and cost factors amenable to intervention.

DESIGN: Prospective cohort study of TB cases at least 15 years of age commencing treatment, interviewed by semi-structured questionnaire and followed for attendance at thrice-weekly directly observed treatment (DOT).
RESULTS: Of 301 patients, 76 (25.2%) defaulted from treatment and 25 did not return for treatment. The defaulting rate was higher among those who said they were uncertain that their treatment would work (HR 3.64; 95%CI 1.42–9.31, $P = 0.007$) and among those who incurred significant time or money costs travelling to

receive treatment (HR 2.67; 95%CI 1.05–6.81; $P = 0.04$). These factors had differing effects with respect to time: uncertainty over treatment success was important in the first 90 days of treatment, while increased cost of travelling to the clinic was important after 90 days.

CONCLUSION: In The Gambia, risk groups for defaulting can be recognised at the start of treatment and are at highest risk at different times. Home-based self-administration of medications after 3 months of DOT should be considered as confidence in treatment success rises, and the costs of travelling to receive treatment start to take their toll.

KEY WORDS: The Gambia; tuberculosis; defaulting; cost; knowledge

TUBERCULOSIS (TB) in The Gambia is on the increase, with all-form case notification rising from 82 per 100 000 population per year in 1994 to 145/100 000/year in 2003.¹ The rate of permanent defaulting from treatment has been consistently above 10% over this time (10–17%), although the rate of resistance to one or more first-line drugs is low (4% in 1999).² Facilities for diagnosis and treatment are provided through nine divisional health centres and a sanatorium. Since 2000, Greater Banjul, the largest urban centre, has experienced rapid population growth and an increasing incidence of TB (176/100 000 in 2003). One major clinic (Serrekunda) in Greater Banjul manages the diagnosis and treatment of almost half the cases for the whole country (930/1985 in 2003), and has experienced increasing congestion and increasing rates of defaulting from treatment.

Following investigations into the qualitative determinants of TB control,^{3,4} we investigated risk factors for defaulting from treatment at the main TB clinic in Greater Banjul, to provide important information for planning the readjustment of services. Most previous

investigations of risk factors for defaulting have used a case control design. Cohort studies are less common but, at least in industrialised countries, have shown that certain risk groups for defaulting can be recognised at the start of treatment.⁵ We used a cohort study design to identify patient characteristics that lead to higher rates of defaulting from treatment, especially patient knowledge and cost factors that might be amenable to intervention.

METHODS

Study participants

New cases of TB aged ≥ 15 years who started their treatment between 16 October 2002 and 26 November 2003 were recruited at the main public TB clinic in Greater Banjul. A case was defined as an individual placed on full course TB treatment, and included smear-positive (Ziehl-Neelsen stain), smear-negative and extra-pulmonary cases. Retreatment cases were not eligible for the study. The majority of smear-negative cases are referred with chest X-ray findings consistent

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with TB. Cases were invited to take part in the study within 3 weeks of starting treatment.

Study participants received standard TB treatment according to current practice in The Gambia, consisting of three times weekly directly observed treatment (DOT), with 2 months of rifampicin (RMP), isoniazid (INH), pyrazinamide and ethambutol, followed by at least 4 months of RMP and INH (8-month treatment for extra-pulmonary TB [EPTB]). Medications were administered by Leprosy/TB Inspectors (LTIs), who are members of the local community trained specifically in the diagnosis and treatment of TB.

Data collection

Study participants answered a structured questionnaire administered in their own language by one of two trained health workers. Information collected in the questionnaire included basic demographic data (age, sex, ethnicity), knowledge of TB, financial resources, and the costs experienced in accessing treatment (including travelling time). After data collection, participants were provided with counselling on the nature and treatment of TB, with specific reference to knowledge deficits identified during administration of the questionnaire.

Information on patients' attendance for treatment was recorded in a separate register. This study was a prospective cohort study with a primary outcome of defaulting, which was defined as failure to present for DOT on three consecutive occasions. Patients were defined as permanent defaulters if they did not return to complete their treatment. LTIs traced patients in their homes where possible.

All patients included in the study provided signed informed consent. The study was approved by the combined Gambia government/MRC ethics committee.

Data management and analysis

All data were double-entered into an Access database (Microsoft Corp, Redmond, WA, USA), verified and checked for errors. Data were analysed by Cox proportional hazards regression to assess the relationship between risk factors and rate of defaulting. Results were reported as unadjusted and adjusted hazard ratios and their 95% confidence intervals (CI). Variables for the multivariable model, apart from age (selected a priori), were included if they showed a univariate association with defaulting at the $P < 0.2$ level of significance. Because, for several factors, there was failure to meet the proportionality assumption necessary for the Cox regression over the whole treatment period, two separate analyses were conducted with time split at 90 days. Kaplan-Meier curves were created for key risk factors. All statistical analyses were conducted using Stata software (Version 8; Stata Corp, College Station, TX, USA).

Table 1 Characteristics of 301 study patients and the eligible clinic population ($n = 937$)

Characteristic	Study participants % (n)	Eligible clinic population % (n)
Sex		
Female	34.2 (103)	34.2 (320)
Male	65.8 (198)	65.9 (617)
Age, years		
15–25	32.9 (99)	28.2 (265)
26–40	42.9 (127)	41.7 (391)
>40	24.9 (75)	30.0 (281)
Type of disease		
Smear-positive	83.4 (251)	67.5 (628)
Smear-negative	11.0 (33)	19.0 (178)
Extra-pulmonary	5.7 (17)	5.7 (53)

RESULTS

From 16 October 2002 to 26 November 2003, 348 TB patients were interviewed; 301 of these (86%) had complete recruitment and follow-up information. The characteristics of the 301 patients are presented in Table 1, together with the characteristics of those who were not interviewed over the course of the study, according to the clinic records. Almost one third of the eligible patients were included in the study and appeared representative for age and sex and for a pulmonary vs. extra-pulmonary diagnosis. However, sputum smear-positive cases were over-represented among the pulmonary cases in the study. No clear reasons for this were identified.

The outcomes of the patients in the study are presented in Figure 1. There were 76 (25.2%) defaulters. The mean time to default was 110 days (median 115; range 21–195 days). Twenty-five patients (33% of the defaulters; 8% overall) were permanent defaulters; 21 of these patients were found to be alive, but four could not be located due to incorrect home addresses.

An assessment of various possible risk factors for defaulting is presented in Table 2, split on time to before 90 days and after 90 days, as described in the methods. Defaulting did not depend on sex, ethnic group or employment status. Patients in the 26–40 years age group had a higher rate of defaulting in the first 90 days of treatment than the other age groups, although this was not statistically significant. Those

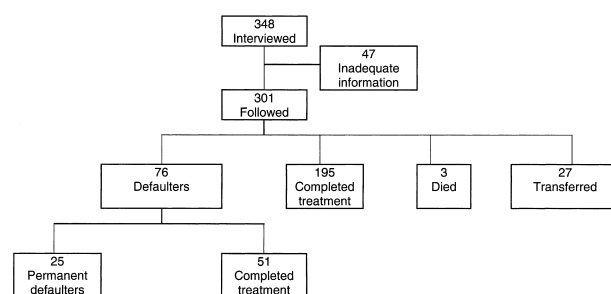


Figure 1 Outcome of study participants.

Table 2 Risk of defaulting by baseline characteristics

Characteristic	Total n (%)	Default (n = 76) n (%)	0–90 days of treatment			After 90 days of treatment		
			Univariate HR (95%CI)	P	Adjusted HR (95%CI)	Univariate HR (95%CI)	P	Adjusted HR (95%CI)
Sex								
Female	103 (34.2)	22 (21.4)						
Male	198 (65.8)	54 (27.3)	1.0	0.58		1.58 (0.82–3.01)	0.17	1.41 (0.70–2.85)
Age, years								
15–25	99 (32.9)	22 (28.6)			1.0			1.0
26–40	127 (42.2)	39 (30.7)	2.99 (0.99–9.02)	0.051	2.96 (0.97–9.06)	1.14 (0.62–2.10)	0.67	1.02 (0.55–1.90)
>40	75 (24.9)	15 (20)	2.43 (0.71–8.30)	0.16	1.98 (0.56–6.92)	0.64 (0.28–1.47)	0.30	0.65 (0.28–1.52)
Ethnicity								
Fula	43 (14.3)	9 (20.9)	1.0			1.0		
Jola	55 (18.3)	16 (29.1)	1.70 (0.43–6.80)	0.45		1.45 (0.53–3.98)	0.47	
Mandinka	135 (44.9)	36 (26.7)	1.31 (0.37–4.66)	0.67		1.34 (0.55–3.27)	0.53	
Wolof	29 (9.6)	5 (17.2)	1.59 (0.32–7.86)	0.57		0.50 (0.10–2.46)	0.39	
Other	39 (13.0)	10 (25.6)	0.73 (0.12–4.38)	0.73		1.48 (0.51–4.26)	0.47	
Type of disease								
Pulmonary	284 (94.4)	70 (24.6)	1.0		1.0	1.0		
Extra-pulmonary	17 (5.6)	6 (35.3)	2.88 (0.99–8.37)	0.051	3.64 (1.14–11.71)	0.73 (0.18–3.03)	0.67	
Employed								
Yes	242 (80.4)	64 (26.4)	1.0	0.32		1.0	0.11	1.0
No	59 (19.6)	12 (20.3)	1.55 (0.65–3.69)			0.47 (0.19–1.18)		0.54 (0.20–1.46)
Family history of disease								
Yes	149 (49.5)	34 (22.8)	1.0	0.32		1.0	0.66	
No	152 (50.5)	42 (27.6)	1.61 (0.73–3.54)			1.13 (0.65–1.98)		
Key TB knowledge*								
Yes	275 (81.1)	66 (27.0)	1.0		1.0	1.0		
No	57 (18.9)	10 (17.5)	0.34 (0.08–1.43)	0.14	0.29 (0.07–1.23)	0.69 (0.33–1.48)	0.34	
Certain of treatment success								
Yes	158 (52.5)	32 (20.3)	1.0	0.003	3.64 (1.42–9.31)	1.24 (0.71–2.16)	0.45	
No	143 (47.5)	44 (30.8)	4.03 (1.62–10.04)			1.0		
Pretreatment cost								
<100 Dalasis	113 (37.5)	26 (23.0)	1.0	0.11	1.61 (0.64–4.09)	1.0	0.96	
≥100 Dalasis	188 (62.4)	50 (26.6)	2.09 (0.84–5.20)			0.99 (0.56–1.73)		
Travel to clinic								
<1/2 h and ≤6 Dalasis†	50 (16.6)	7 (14.0)	1.0	0.19	1.29 (0.29–5.71)	1.0	0.084	1.0
>1/2 h or >6 Dalasis	251 (83.4)	69 (27.5)	2.60 (0.62–11.02)			2.26 (0.90–5.69)		2.67 (1.05–6.81)
Financial stress of treatment‡								
No	88 (29.2)	21 (23.9)	1.0	0.22		1.0	0.94	
Yes	213 (70.8)	55 (25.2)	0.54 (0.21–1.44)			1.02 (0.57–1.86)		

* TB can be given to someone else, it can kill and it can be cured.

† Six Dalasis = 0.16 Euros, equivalent to an average taxi fare in The Gambia.

‡ Loss of >3 days work per week, needing to pay children's school fees or having to borrow money due to treatment in the absence of any financial help.
HR = hazard ratio; CI = confidence interval; TB = tuberculosis.

with extra-pulmonary disease, although small in number, had a higher rate of defaulting in the first 90 days than those with pulmonary disease; this was significant in the multivariable model ($P = 0.03$). As the fact that extra-pulmonary cases each contributed 8 months of time to the study did not affect the results, a separate analysis was not required.

Other risk factors were combined on the basis of the questionnaire. Those with a family history of disease included those with a family history of TB or any other severe illness (such as severe malaria); they were not more likely to default. Key TB knowledge included an understanding that TB can be given to someone else, that it can kill and that it is curable. Those lacking in one or more key knowledge areas surprisingly had a lower rate of defaulting in the first 90 days of treatment, although this was not statistically significant. In contrast, those who were not certain that their treatment would be successful were at an increased risk of defaulting in the first 90 days; this remained statistically significant in the multivariable analysis ($P = 0.007$). Notably, this was not a significant risk factor for defaulting after 90 days.

Pre-treatment costs included visits to traditional healers, other alternative health care providers or health clinics before TB was diagnosed. Those with greater pre-treatment costs did not have a significantly increased rate of defaulting. Cases who had to travel for more than half an hour or incurred more than 6 Dalasis (0.16 Euros, equivalent to an average taxi fare in The Gambia) to reach the treatment centre were at an increased risk of defaulting after 90 days of treatment, compared to those with neither problem; this was statistically significant in the multivariable analysis ($P = 0.04$).

Financial stress during treatment was defined as a loss of more than 3 days' work per week, the need to pay children's school fees, or having to borrow money over the period of treatment, in the absence of financial help from others. Financial stress was not associated with defaulting.

Kaplan-Meier plots of time to defaulting according to level of certainty of treatment success (A) or difficulty in travel to clinic (B) are presented in Figure 2. The difference in the rate of defaulting for each risk factor, compared with those without the risk factor, was consistent with the findings of the Cox regression: both had a divergence that began at approximately 3 weeks, increasing most dramatically in the first 90 days for those with uncertainty about treatment outcome, and increasing more slowly during the first 90 days with respect to significant travel time or cost of travel to the clinic.

DISCUSSION

In this prospective cohort study of defaulting from TB treatment in The Gambia, we found that the rate of

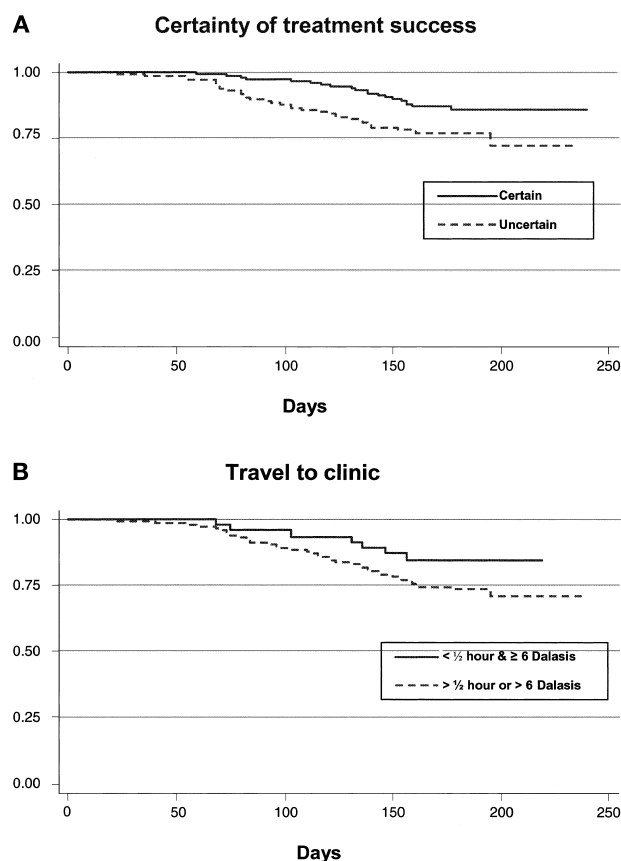


Figure 2 Kaplan-Meier plots of time to defaulting for key risk factors, adjusted for possible confounding variables.

defaulting significantly increased in TB patients who were uncertain that their treatment would work and in those who incurred significant time or money costs when travelling to receive treatment. These two factors had differing effects with respect to time: uncertainty over treatment success was important in the first 90 days of treatment, while increased costs of travelling to the clinic became important after 90 days. Subjects with extra-pulmonary disease were also at a higher risk of defaulting than those with pulmonary disease. None of the following factors had any effect on defaulting: age, sex, ethnicity, employment status, previous experience of a severe disease or reported financial stress while on treatment.

Knowledge about TB disease and its treatment at the time of defaulting have been shown to be important in case control studies in Africa.^{6,7} In our study, however, those with an essential knowledge deficit were not more likely to default from treatment than those with no deficit. Strangely, it appeared that the opposite might be true, although the effect was not statistically significant. Another cohort study of 135 patients in Malaysia found misconceptions and limited knowledge about TB among the participants, but found also that these had no effect on defaulting.⁸ These findings may be an artefact due to the information bias introduced by health workers endeavouring

to correct knowledge deficits identified in the questionnaire. This is a weakness inherent in the design of a cohort study, where it is considered unethical to ignore knowledge deficits when found. Perhaps a more accurate reflection of health belief was the 'uncertainty of treatment success', which was significantly associated with defaulting in the first 90 days. It is quite reasonable to surmise that improving symptoms would lead those with uncertainty to become more confident of treatment success, explaining the loss of a difference after 90 days.

Others have also shown increased rates of defaulting associated with difficulty in getting to treatment.⁹ Our study, combining cost in terms of time and money spent, shows that in The Gambia this risk becomes particularly important after the first 3 months of treatment. We suggest that the effect of cost incurred getting to treatment builds up over time, explaining this finding.

Defaulting has also been associated with male sex¹⁰⁻¹⁴ and HIV positivity^{11,13} in studies from India, South Africa, Ethiopia and The Gambia. In contrast, we did not find any significant gender difference for defaulting in our study, although after 90 days there was a trend towards an increased rate in males ($P = 0.17$). The rate of defaulting from treatment has been shown by others to be increased in patients with EPTB, and is likely to be related to HIV positivity.¹⁵ As we did not assess HIV status under the routine programme conditions of this study, it is a potential source of bias. In The Gambia less than 10% of TB patients are HIV-positive,¹⁶ although the prevalence is likely to increase. It is the intention of the National TB Control Programme to introduce routine HIV testing among TB patients in the near future.

Studies in America, Canada, Hong Kong and Ethiopia have found older age, especially over 60 years, to be associated with higher rates of defaulting.^{7,17-19} In contrast, as has also been documented in South Africa,¹² we found that the 26-40 year age group appeared more likely to default (in the first 90 days of treatment, $P = 0.057$). These differences certainly warrant further study.

The results of this study have provided important information for policy makers in The Gambia. We have shown that risk groups for defaulting can be recognised at the start of treatment and are at highest risk at different times. Since the completion of the study, there has been some decentralisation of treatment to alleviate congestion at the clinic and improve access. Strategies to improve knowledge about TB in ways that change basic beliefs about the likely success of treatment will be important.²⁰ A combination of decentralisation and an extended range of DOT supervision options has improved treatment outcomes in Malawi.²¹ It may also be worthwhile to consider 'self-supervised' treatment after the first 3 months.²² Such a strategic, focused, mixed DOT and self treat-

ment plan would make sense, as uncertainty over treatment success appears to decrease over time on medications, while the toll from costs incurred in getting to treatment rises.

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R É S U M É

SETTING : Polyclinique pour la tuberculose (TB) en milieu urbaine, Gambie.

OBJECTIF : Identifier les caractéristiques du patient associées à une augmentation des taux d'abandon du traitement, et spécifiquement les connaissances et les facteurs de coût susceptibles d'être améliorés par une intervention.

SCHÉMA : Etude prospective de cohorte de cas de TB âgés d'au moins 15 ans et commençant leur traitement, interviewés grâce à un questionnaire semi-structuré et suivi en ce qui concerne leur participation à un traitement directement observé (DOT) administré trois fois par semaine.

RÉSULTATS : Parmi les 301 patients, il y a eu 76 abandons du traitement (25,2%) ; 25 d'entre eux ne sont pas revenus pour le traitement. Le taux d'abandon a été plus élevé chez ceux qui disaient avoir des doutes au sujet de l'activité de leur traitement (HR 3,64 ; IC95% 1,42–

9,21 ; $P = 0,007$) et chez ceux qui encouraient des coûts significatifs en temps et en argent pour se rendre à leur traitement (HR 2,67 ; IC95% 1,05–6,81 ; $P = 0,04$). Ces facteurs ont eu des effets différents à des moments différents : l'incertitude concernant les succès du traitement a été importante au cours des 90 premiers jours du traitement, alors qu'un coût accru pour se rendre à la polyclinique a été important après 90 jours.

CONCLUSION : En Gambie, les groupes à risque d'abandon peuvent être reconnus dès le début du traitement et le risque encouru est le plus élevé à des moments différents. Il y a lieu d'envisager une auto-administration des médicaments basée sur le domicile après 3 mois de DOT, au moment où la confiance concernant le succès du traitement augmente et où les coûts d'obtention du traitement commencent à se faire ressentir.

R E S U M E N

MARCO DE REFERENCIA : Un consultorio urbano de tuberculosis (TB), en Gambia.

OBJETIVO : Identificar las características de los pacientes, asociadas con un alto índice de abandono del tratamiento antituberculoso, en particular los factores relacionados con el conocimiento de la enfermedad y los costos, sobre los cuales puede programarse una intervención.

MÉTODO : Estudio prospectivo de cohortes de pacientes de 15 años y más con TB, al comienzo del tratamiento. Se practicaron entrevistas a los pacientes mediante cuestionarios semiestructurados y un seguimiento a fin de evaluar la asistencia tres veces por semana al tratamiento directamente observado (DOT).

RESULTADOS : De los 301 pacientes, 76 (25,2%) abandonaron el tratamiento y 25 de ellos no regresaron. La tasa de abandono fue más alta entre quienes decían no estar seguros de la eficacia del tratamiento que recibían (HR 3,64 ; IC95% 1,42–9,31 ; $P = 0,007$) y entre

quienes hicieron una inversión considerable de tiempo o de dinero para recibir el tratamiento (HR 2,67 ; IC95% 1,05–6,81 ; $P = 0,04$). Estos factores tuvieron efectos diferentes según el período del tratamiento : la inseguridad sobre el éxito del tratamiento fue importante durante los primeros 90 días y el alto costo para acudir al consultorio fue importante después de 90 días de tratamiento.

CONCLUSIÓN : En Gambia, los grupos de riesgo de abandono pueden reconocerse al comienzo del tratamiento antituberculoso y presentan su riesgo más alto en diferentes períodos del esquema terapéutico. Se puede pensar en la posibilidad de una auto-administración domiciliar de los medicamentos después de 3 meses de DOT, en la medida en que aumenta la confianza del paciente en el éxito del tratamiento y comienzan a ejercer un efecto negativo los costos de desplazamiento para recibir los medicamentos.